UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,012	06/13/2001	Edward I. Ginns	015280-248120US	8624

7590 03/31/2004

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP
1201 NEW YORK AVE, N.W.
SUITE 1000
WASHINGTON, DC 20005

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/881,012	GINNS ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on 03 March 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 1-12, 15-26.

Claim(s) withdrawn from consideration: 13,14 and 27.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

J. Goldberg

JEFFREY FREDMAN
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance.

The response argues that the claims are drawn to screening methods of genotypes to determine whether a genotype is associated with increased bipolar affective disorder. Applicant argues selection of variants is routine. This is not correct because it is entirely unpredictable if there are variants. In fact, Applicant is attempting to claim this subject matter because it is not routine. It is entirely unpredictable and inventive whether any particular microsatellite marker, translocation, mutation, deletion, splice variant or polymorphism is associated with BPAD. In particular, this unpredictability, combined with the other factors, supports a conclusion of undu experimentation.

Unlike the simple screening assay in Wands itself, where experimental success was assured so long as sufficient resources were expended, since eventually an antibody producing cell would be isolated, here there is no assurance or even likelihood of success, since there is no reason to believe that other polymorphisms necessarily exist which have the desired correlation. At the time of the invention, it is speculative and without evidentiary basis to predict if there will be any results from the screening for additional polymorphisms, unlike Wands where it is not only possible but expected that results will be achieved. Here, there is no expectation that other polymorphisms associated with BPAD will be found.

It is noted that the claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." State Street, 149 F.3d at 1373, 47 USPQ2d at 1601-02. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research (Brenner v. Manson, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96); In re Ziegler, 992, F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)). The claimed invention is an idea for future investigation or research. The exact purpose of the method is to determine whether additional genotypes are associated with BPAD.

It is acknowledged that there is at least one marker within each of the claimed regions which is correlated, however there are also severa markers which are not correlated. It is noted that each of these regions is extremely large. For example the region on chromosome 4 is a range of 33.3cM and 42.8cM. These are much larger than the attorney arguments stating that "one would reasonably expect that marker located at about 10cM from a marker would be linked to that marker. It is noted that this is attorney arguments. The submission of the post filing date article to try and establish the current practice in the field is not appropriate (page 10 of response). The enablement of an invention is determined at the time of filing. The instant filing date is 1997. Therefore, the state of the art in 2003 is not at the time the invention was made. As provided by MPEP 2164.05, "To overcome a prima facie case of lack of enablement, applicant must demonstrate by argument and/or evidence that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time o filing."

The response fails to address the lack of any data on chromosome 11, as required by Claim 1.

The response traverses the rejection because the allegation that other studies of linkage in BPAD may have been faulty does not case doubt on the accuracy or significance of the present findings. This argument has been thoroughly reviewed, but is not found persuasive because the data provided by Berrettini, for example, provides that it is unpredictable that genotypes in this region are associated with BPAD. The response fails to provide any objective evidence of record that Berrettini does not cast doubt on the accuracy of linkage. The Berrettini reference specifically discusses that independent confirmation is required prior to acceptance of linkage and the linkage of a BP locus on 11p15 is weakened by failure to confirm this putative locus with other populations (page 289).

The response asserts that the fact that markers within a region of interest may not appear significantly correlated with BPAD does not cas doubt on the conclusion that the region is correlated with BPAD. This argument has been thoroughly reviewed, but is not found persuasive because the claims are not drawn to a method for determining a region associated with BPAD, but rather a method for determining a genotype or a marker which is associated with increased resistance to BPAD. Moreover, applicants arguments are not supported by any objective evidence of record. The fact that there are markers within the region which do not show association illustrates the unpredictability of the invention.

The response asserts that the Blackwood reference cited which identifies some of the markers on 4p as associated with susceptibility are not problematic to the instant disclosure providing they are protective (page 12 of the response). This argument has been thoroughly reviewed, but is not found persuasive because it is unpredictable whether each marker will be associated with resistance to bipolar disease since there are some in the region where are associated with protective for BPAD. Further, as discussed above, the post-filing date art is not pertinent to the enablement at the time the invention was filed.

The response correctly argues that the specification provides the general method for screening individuals for particular predispositions. The basic method is well know method for comparing and determining whether an association exists, however, the outcome of each of th markers encompassed by the claims is unpredictable and undue experimentation. Just because the method can be performed does not enable the skilled artisan to make the specific genotypes. The nature of alleles and markers are such that the general knowledge in the art concerning one allele does not provide any indication of how the structure of one alleles is representative of unknown alleles. They ar variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others and the enablement of the others.

With respect to the description issue, the specification fails to provide any deletions, translocations, SNPs, or mutations which are within the scope of the genus.